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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,803	02/09/2004	Ralph A. Heasley	XANO-42	9066

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WOOD, HERRON & EVANS, LLP
2700 CAREW TOWER
441 VINE STREET
CINCINNATI, OH 45202

EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/774,803	HEASLEY, RALPH A.	
	Examiner	Art Unit	
	Umamaheswari Ramachandran	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-93* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-93 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 20 drawn to a formulation comprising a therapeutically effective amount of levomepromazine, EDTA and monothioglycerol (MTG) or glutathione, classified in class 514, subclass 225.8.

II. Claims 21-41, 62 drawn to a formulation comprising a therapeutically effective amount of levomepromazine, EDTA, monothioglycerol or glutathione, ascorbic acid, classified in class 514, subclass 225.8.

III. Claims 42-61 drawn to a formulation comprising a therapeutically effective amount of levomepromazine, EDTA, ethylgallate or cysteine and ascorbic acid, classified in class 514, subclass 225.8.

IV. Claim 63 drawn to a formulation comprising a therapeutically effective amount of levomepromazine HCl, ascorbic acid, EDTA and MTG, classified in class 514, subclass 225.8.

V. Claims 64-65 drawn to a stable terminally sterilized formulation comprising a therapeutically effective amount of levomepromazine wherein said formulation contains a concentration of total impurities of less than about 3% by weight per volume of the formulation and is terminally sterilized, classified in class 514, subclass 225.8.

VI. Claims 66-73, drawn to a method of stabilizing a formulation of levomepromazine, comprising levomepromazine, EDTA, MTG or glutathione and sparging said formulation with an oxygen-free inert gas, classified in class 514, subclass 225.8.

VII. Claims 74-82 drawn to a method for stabilizing a formulation of levomepromazine comprising a therapeutically effective amount of levomepromazine, EDTA, MTG and ascorbic acid, classified in class 514, subclass 225.8.

VIII. Claims 83-90 drawn to a method for stabilizing a formulation of levomepromazine comprising levomepromazine, EDTA, ethylgallate or cysteine and ascorbic acid and sparging said formulation with an oxygen-free inert gas, classified in class 514, subclass 225.8.

IX. Claims 1, 91 drawn to a method of treating a disorder in a patient in need thereof, comprising administering a formulation a therapeutically effective amount of levomepromazine, EDTA and monothioglycerol (MTG) or glutathione, classified in class 514, subclass 225.8.

X. Claims 21, 92 drawn to a method of treating a disorder in a patient in need thereof, comprising administering a formulation a therapeutically effective amount of levomepromazine, EDTA, monothioglycerol or glutathione, ascorbic acid, classified in class 514, subclass 225.8.

XI. Claims 42, 93 drawn to a method of treating a disorder in a patient in need thereof, comprising administering a formulation a therapeutically effective

amount of levomepromazine, EDTA, ethylgallate or cysteine and ascorbic acid, classified in class 514, subclass 225.8.

The inventions are distinct from each other because of the following reasons:

Inventions of Groups I-V and VI-XI are related to formulation and method of stabilizing the product or using the product. The inventions are distinct if either or both of the following can be shown: (1) that the method as claimed can be carried out with a different product or (2) that the product as claimed can be used for a different method. In the instant case the method in the claims can use a different product such as metoclopramide and a long lasting NSAID to treat migraine (U.S. 6,077,539).

Groups I-V is related as formulation comprising levomepromazine and Groups VI-XII are directed to a method of stabilizing or treating a disorder comprising levomepromazine. Groups I-V are directed to formulation comprising a therapeutically effective amount of levomepromazine and different stabilizers, VI-VIII are directed to a method of stabilizing a formulation of levomepromazine, IX-XII are directed to a method of treating a disorder in a patient in need thereof, comprising administering a formulation a therapeutically effective amount of levomepromazine with different stabilizers.

The searches of Groups I -XII may be overlapping but there is no reason to believe that the searches would be co-extensive. The search required for Groups I-V are not required for Groups VI - XII, restriction for examination purposes as indicated is proper. The examiner will be focusing on the patentability of the different methods and not the composition for the group VI - XII searches. Conversely, in searching Groups I-V the examiner will be focusing on the patentability of the composition and not the method

of treatment. The search for each group will focus on formulations or methods comprising levomepromazine with different stabilizers and hence the search for all inventions would place an undue burden on the Office in view of the corresponding diversity in the field of search for each.

The examiner has required restriction between process and product claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection is governed by 37 CFR 1.116; amendments submitted after allowance is governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between products claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The application contains claims directed to patentably distinct species of the claimed invention. The search for each disorder would represent an undue burden on the office in view of the different classes to be searched. If Applicant elects Group IX or X or XI applicant is further required to elect a species for a disorder.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C 103(a) of the other invention.

Election

A telephone call to the attorney is not required where 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the examiner knows from past experience that a telephone election will not be made (MPEP

§ 812.01). Therefore, since the examiner knows from past experience that written restriction is preferred, a telephone election was not made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SUPERVISORY PATENT EXAMINER